World Health Organization

SIXTY-FOURTH WORLD HEALTH ASSEMBLY **A64/17**
Provisional agenda item 13.8 **17 March 2011**

Smallpox eradication: destruction of variola virus stocks

Report by the Secretariat

1. In resolution WHA60.1 on smallpox eradication: destruction of variola virus stocks, the World Health Assembly requested the Director-General to undertake a major review in 2010 of the results of the research undertaken, currently under way, and the plans and requirements for further essential research for global public health purposes, taking into account the recommendations of the WHO Advisory Committee on Variola Virus Research, so that the Sixty-fourth World Health Assembly in 2011 might reach global consensus on the timing of the destruction of existing variola virus stocks. The Health Assembly, inter alia, also requested the Director-General to continue the work of that Committee; maintain biannual inspections of the two authorized repositories of variola virus; and develop continually the operational framework for WHO's smallpox vaccine reserve.

2. This document reports on the progress made in response to those requests and summarizes the outcome of the twelfth meeting of the WHO Advisory Committee on Variola Virus Research (Geneva, 17–18 November 2010).

SECRETARIAT ACTIONS

Major review of variola virus research

3. Following the adoption of resolution WHA60.1 in May 2007, the Director-General commissioned the WHO Advisory Committee on Variola Virus Research to oversee a major review of variola virus research.

4. At its ninth meeting in November 2007, the Advisory Committee proposed that a summary of the research conducted on and with variola virus be drafted for consideration by the Sixty-fourth World Health Assembly.[1] At the subsequent meeting in November 2008, the Advisory Committee decided that, in preparing the major review of the research performed from 1999 to 2010, the following approach would be used: a group of scientists representing all areas of research and development on orthopoxviruses, and endorsed by the Advisory Committee, would review comprehensively both the published scientific literature and the unpublished data concerning live variola virus research. In turn, this comprehensive review would be externally reviewed by a group of independent experts from outside the variola virus field.

[1] For reports of the ninth, tenth and eleventh meetings, see documents A61/6, A62/23 and A63/19.

5. Following the tenth meeting of the Advisory Committee and under its supervision, a group of scientists endorsed by the Committee, with specific expertise in variola virus or other orthopoxviruses, began drafting the "Scientific review of variola virus research, 1999–2010". The chapters of the review correspond to the following six areas: smallpox vaccines, laboratory diagnostics, variola virus genomics, the status of the two WHO repositories of variola virus, animal models and antiviral agents. At its eleventh meeting in November 2009, the Advisory Committee considered and discussed the review's contents, and work on the review continued until October 2010.

6. The finalized scientific review[1] was considered by a panel of independent experts from outside the variola virus field. In July 2010 the Director-General began appointing experts for the Advisory Group of Independent Experts to review the smallpox programme. Between September and November 2010, the members of that Advisory Group met to finalize their report "Advisory Group of Independent Experts to review the smallpox research programme (AGIES): comments on the scientific review of variola virus research, 1999–2010".

7. At its twelfth meeting, in November 2010, the Advisory Committee considered the six chapters of the scientific review, and the finalized report with the comments of the Advisory Group of Independent Experts.[2]

8. Both the background scientific review and the report of the Advisory Group of Independent Experts were revised in light of the comments made by members of the Advisory Committee at its twelfth meeting. The two reviews and the report of the Advisory Committee meeting were posted on the WHO web site in December 2010.[3]

Archives

9. At its twelfth meeting, the Advisory Committee also discussed access to, and preservation of, WHO archives of the Smallpox Eradication Programme. The paper files have been preserved and the scanned archives have been incorporated in a dedicated database. Plans are in place to make them available on the Internet.

Smallpox vaccine reserve

10. WHO's smallpox vaccine emergency stockpile of 32.6 million doses is stored safely and securely in Switzerland. Nearly all (92%) of this strategic stock is composed of second-generation vaccine. The remaining 8% of the stockpile is first-generation vaccine. In addition, through a virtual stockpile mechanism, five Member States have pledged another 31 million doses to WHO in case of additional need: France, Germany, New Zealand, the United Kingdom of Great Britain and Northern Ireland, and the United States of America. WHO has agreed, or is developing, standard operating procedures with these countries.

[1] Document WHO/HSE/GAR/BDP/2010.3.

[2] Document WHO/HSE/GAR/BDP/2010.4.

[3] Document WHO/HSE/GAR/BDP/2010.5.

Laboratory network

11. On behalf of the Director-General, the Advisory Committee has established a subcommittee whose task is to consider developing a WHO Smallpox Laboratory Network of high-level diagnostic laboratories throughout the world. The purpose of such a network of laboratories would be the rapid and reliable detection of any emergence of variola viruses, and would comprise two reference laboratories, in the Russian Federation and the United States of America, as well as several regional laboratories – one or two in each of the WHO regions. Laboratories in the Smallpox Laboratory Network would not need to store variola virus as they would be using molecular biological techniques that do not involve the live virus.

Biosafety inspection visits

12. WHO biosafety inspection teams visited the two smallpox repositories and inspected the containment facilities in the Russian Federation and the United States of America in 2009. A standardized inspection tool in the form of a laboratory biorisk management standard was field-tested during the visit to both repositories. The WHO biosafety inspection team visited the Centers for Disease Control and Prevention (Atlanta, United States of America) and the State Research Centre for Virology and Biotechnology (Koltsovo, Russian Federation), and found both sites to be safe and secure for work with live variola virus. Reports of these visits are available on the WHO web site.[1]

13. An earlier version of this report was considered and noted by the Executive Board at its 128th session in January 2011.[2]

ACTION BY THE HEALTH ASSEMBLY

14. The Health Assembly is invited to note the report and to provide further guidance, in light of resolution WHA60.1.

= = =